### **REMARKS**

## I. Office Action Summary

Claims 64-81 are pending. Claim 77 is the only independent claim. In the Office Action dated January 4, 2007, claims 77-78, 64-74, 76 and 81 were rejected as obvious over the combination of Chester (WO 82/00413 A1) in view of Smith et al. (U.S. 5,0131,613). Claims 75 and 79-80 were rejected as obvious over the combination of Chester, Smith, and Blake et al. (U.S. 3,634,924).

### II. Claim Rejections Under 35 U.S.C. § 103

# A. Rejection of Claims 77-78, 64-74, 76 and 81 Over Chester in View of Smith

#### CLAIM 77

Independent claim 77 relates to a method of forming a catheter for nebulizing a liquid with a gas where the method includes the steps of:

providing a multilumen extruded polymer tubing;

heating a portion of the tubing to a transition temperature of said tubing;

forming a j-shaped distal section in the multilumen extruded polymer tubing, wherein the multilumen extruded polymer tubing curves away from a longitudinal axis of the catheter at a distal end of the catheter; and

forming a plurality of orifices at the distal section, said plurality of orifices being sized to nebulize a liquid delivered through one of said lumens to form an aerosol with a gas delivered through another of said lumens.

The Chester reference lacks any teaching of at least the above bolded elements of claim 77. Chester discloses medical tubing with embedded radiopaque material in its walls. The Office Action appears to mistake the integrally formed strips of radiopaque material (items 16,18,24,26, 28 and 30 in the Figures) in the wall 14 of the tubing for lumens. The section of Chester cited in the Office Action, p. 3, lines 30-33, continues on in lines 33-36 to state that the radiopaque material is coextruded with the tubing

material. Thus, there is only a single lumen in Chester with two or more strips of radiopaque material embedded in the wall of the single lumen.

Additionally, Chester lacks any teaching or suggestion of forming a j-shape distal section. Applicant notes that neither the cited section of Chester, p. 8, lines 16-21, nor any other part of the text, mention any overall shape or form for the tube. The figures in Chester also lack any teaching or suggestion of forming a j-shape at a distal end.

Smith also fails to teach or suggest the above bolded elements of claim 77. Rather than teaching multilumen extruded polymer tubing, Smith discloses a catheter 2 that is removably placed inside an endotracheal tube 4. Applicant notes that a lumen 40 may be attached on the outside of, and partway down the length of, the endotracheal tube and connected with a balloon 12 on the outside of the endotracheal tube (See FIG. 1). This does not appear to be any type of multilumen extruded polymer tubing and the specification does not teach or suggest that type of construction. Thus, the catheter of Smith is a single hollow tube and does not disclose a multilumen extruded polymer tube as claimed.

Applicant also notes that the separate endotracheal tube 4 in Smith is generally curved along its entire length. The bendable, single-lumen, catheter 2 inserted therein also follows this curve. No j-shape is evident at the distal end of the tube or catheter. Instead, Smith shows a pinched "hour-glass" shaped neck near its distal end 8 (see embodiments of FIG. 2 and FIG. 4 in Smith). Accordingly, Smith also lacks at least the j-shaped distal section where a multilumen extruded polymer tubing curves away from a longitudinal axis of the catheter at a distal end of the catheter.

Because of the complete lack of disclosure or suggestion of the elements of claim 77 in Chester and Smith, alone or in combination, Applicant submits that claim 77 is allowable over the art of record. Claims 64-76 and 78-81 are dependent claims, therefore their allowability directly follows from the allowability of independent claim 77. Reconsideration and allowance is respectfully requested.

# B. Rejection of Claims 75 and 79-80 Over the Combination of Chester, Smith and Blake

Applicant respectfully disagrees with the Examiner's rejection and submits that, in addition to the patentably distinct features recited in these claims, dependent claims



75 and 78-79 are allowable for at least the same reasons as provided for independent claim 77.

Blake fails to make up for the deficiencies of Chester and Smith. The Examiner previously noted (Office Action dated April 6, 2006, p.6) that Blake lacks any teaching or suggestion of a j-shaped distal end. Applicant agrees that Blake lacks at least this feature of claim 77. Additionally, Applicant notes that the catheter disclosed in Blake is a balloon catheter having "a soft and limp tube" (col. 1, line 45). As recited in Blake, "the catheter tube has a balloon inflation lumen 53 and a through flow lumen 54, the tube being flexible to the extent of being completely limp" (col. 3, lines 5-7). The disclosure of Blake goes on to further emphasize the straight-ended catheter through its discussion of the balloon that is inflated to prevent the tip of the catheter from damaging a heart or artery wall. Specifically, the disclosure recites:

when the balloon 60 is inflated, the annular bulge 65 prevents point contact of the tip of the catheter tube with the heart or artery wall. The presence of the balloon around the tip of the catheter alters the catheter system from one with a point force to one with forces dispersed over a surface. (col. 4, lines 10-12)

Thus, not only does Blake fail to teach or suggest a j-shaped distal section as claimed, it also teaches away from such a feature through its discussion of the completely limp tube and the balloon to disperse pressure that might otherwise be focused at the point of the catheter. Accordingly, there is no motivation to combine Blake with a catheter having a j-shaped distal section either.

Furthermore, the reference made in the Office Action to a wire in the Blake reference is inapposite. The cited passage in Blake relates to a wire "inserted temporarily" into a lumen while a tip section is being formed and then removed (Blake, Col. 2, lines 38-45) and not to a wire embedded in the tube to fabricate a radiopaque stripe, as recited in dependent claim 75, or to steps of attaching a tether to a shaft of the catheter and an end of a j-shaped distal section as recited in claims 79-80.

Applicants submit that claims 75 and 79-80 are allowable for at least these additional reasons.

### III. Conclusion

With the above remarks and amendments, Applicant submits that claims 64-81 are in condition for allowance. Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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